REMARKS

Reconsideration of the present application in view of the above amendments and following remarks is respectfully requested. Claims 1-20 and 30-36 were pending. Applicants submit that claims 7 and 20 have been hereby amended for mere editorial purposes to correct obvious inadvertent typographical errors (*i.e.*, the scope of the claims have not changed) and not for reasons of patentability. In addition, Applicants hereby submit new claim 37, support for which may be found in the application as originally filed, in part, at page 8, lines 7-11; or at page 9, lines 1-3. No new matter has been added. Therefore, claims 1-20 and 30-37 are currently pending.

CLAIM OBJECTION

In the Office Action dated May 7, 2003, claim 7 was objected to for the use of commas around the word "or". Applicant wishes to thank the Examiner for identifying this inadvertent typographical error. As requested and set forth above, the commas before and after "or" have been removed in claim 7. Accordingly, Applicants respectfully submit that this objection has been obviated and, therefore, request that it be withdrawn.

REJECTION FOR STATUTORY DOUBLE PATENTING UNDER 35 U.S.C. § 101

Claims 1-20, 30, 31 and 33-36 have been provisionally rejected under 35 U.S.C. § 101 as claiming the same invention as that of claims 1-20, 30, 31 and 33-36 of co-pending U.S. Patent Application No. 09/859,899.

Applicants respectfully submit that this ground of rejection has been rendered moot because claims 1-20, 30, 31 and 33-36 of co-pending U.S. Patent Application No. 09/859,899 were cancelled without prejudice. Accordingly, Applicants respectfully request that this rejection be withdrawn.

REJECTION UNDER OBVIOUSNESS-TYPE DOUBLE PATENTING

Claim 32 has been provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 32 of co-pending U.S. Patent Application No. 09/859,899.

Applicants respectfully submit that this ground of rejection has been rendered moot because claim 32 of co-pending U.S. Patent Application No. 09/859,899 was cancelled without prejudice. Accordingly, Applicants respectfully request that this rejection be withdrawn.

THE PRESENT INVENTION

The present invention is generally directed to stent grafts. Stent graft are devices that may be placed within a patient's blood vessel in order to, for example, hold open the blood vessel and/or bridge across diseased vasculature from healthy vessel to healthy vessel (*see, e.g.*, specification at page 1, lines 12-14). A problem with stent grafts is that they have a tendency to migrate distally within the blood vessel and such migration results in device failure, perigraft leak, and vessel occlusion (*see, e.g.*, specification at page 3, lines 14-16). The present invention addresses this problem in a manner that is neither taught nor suggested by the prior art. More specifically, the present invention is directed to a stent graft that may be inserted into, for example, a blood vessel, whereupon the stent graft releases an agent that induces the *in vivo* adhesion of the stent graft to vessel walls. The agent, thus, promotes the adhesion of the stent graft to the vessel wall (*see, e.g.*, specification at page 6, lines 17-19).

REJECTIONS UNDER 35 U.S.C. § 103(a)

(a) In the Office Action, claims 1-17 and 30-36 were rejected under 35 U.S.C. §103(a) as obvious over U.S. Patent No. 5,723,004 (Dereume *et al.*) in view of U.S. Patent No. 5,744,515 (Clapper). More specifically, it is alleged that it would have been obvious for a person having ordinary skill in the art to employ an adhesive material as disclosed by Clapper in the vascular graft of Dereume *et al.* in order to promote the attachment between the stent graft and wall vessels according to the instant invention. In addition, it is alleged that a mere substitution of one adhesive agent for another known in the art (as disclosed in U.S. Patent Nos.

6,113,629, Ken, and 5,607,475, Cahalan *et al.*) would have been obvious for a person having ordinary skill in view of Dereume *et al.* and Clapper.

Applicants respectfully traverse this ground of rejection and submit that Dereume *et al.* and Clapper, taken alone or in combination, fail to teach or suggest the claimed invention and, further, would not have motivated a person having ordinary skill in the art to arrive at the claimed invention with a reasonable expectation of success. Briefly, where claimed subject matter has been rejected as obvious in view of a combination of prior art references, a proper analysis under §103 requires, *inter alia*, consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process; and (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success. *In re Vaeck*, 947 F.2d 488, 20 USPQ.2d 1438 (Fed. Cir. 1991).

In the instant case, the cited references meet neither of these criteria. Dereume *et al.* describe an endoluminal graft (not a stent graft) made of an expandable support mesh covered and lined with a material that is porous and elastomeric (*see* Dereume *et al.*, Abstract). The problem addressed by Applicants' invention, namely unwanted movement of the graft after it has been inserted into a vessel, is addressed by Dereume *et al.* through mechanical means, for example, through the use of staples (*see* Dereume *et al.* at col. 6, lines 24-47 for a discussion of how Dereume *et al.* inhibit movement of a stent within the vessel).

As noted by the Examiner, Dereume *et al.* disclose that a drug may be located on the surface of the Dereume *et al.* grafts. However, the only reason given by Dereume *et al.* for placing a drug on a graft is to create a more biocompatible graft. Dereume *et al.* also list some drugs, specifically antibiotics and steroids, that appear directed to providing a therapeutic effect to the patient that has received the stent (*see* Dereume *et al.* at column 10 line 60 through column 11, line 2). Accordingly, Dereume *et al.* fail provide any teaching or suggestion to locate an agent on the graft that releases an agent which induces the *in vivo* adhesion of a stent graft to vessel walls. In fact, the drugs suggested for use on the Dereume *et al.* grafts are for entirely different purposes than the goal of Applicants' invention, and the goal of Applicants' invention is addressed in an entirely different way (*i.e.*, mechanically) in the grafts of Dereume *et al.*

Applicants respectfully submit that the disclosure of Clapper fails to remedy the deficiencies of Dereume *et al.* and, therefore, the combination of Dereume *et al.* with Clapper fails to teach or suggest the instant invention. Clapper discloses an article comprising an implantable medical device formed of a porous, rigid biomaterial that provides a surface bearing an immobilized adhesion molecule in an amount and type suitable to promote capillary endothelialization through the surface and into the device when used in vivo (see, e.g., Abstract and col. 6 lines 49-54). Clapper discloses that the significance of capillary endothelialization will vary with each particular device, depending on the type and purpose of the device. Ingrown capillaries can be useful for providing perfusion into the device to carry nutrients to cells in the device and to carry away waste products. Ingrown capillaries can also be useful for providing endothelial cells to line the surface of vascular grafts to improve blood compatibility. However, Clapper does not disclose that capillary endothelization is a mechanism for inducing the *in vivo* adhesion of a stent graft to vessel walls. Thus, Clapper does not make up the deficiencies of Dereume *et al.* because Clapper does not teach or suggest the use of a stent graft, Clapper does not teach or suggest a stent graft that releases an agent which induces *in vivo* adhesion, and Clapper does not teach or suggest a stent graft that induces or accelerates an *in vivo* fibrotic reaction. Hence, even the combination of Dereume *et al.* and Clapper fail to teach or suggest every limitation of the claimed invention.

Accordingly, even assuming, *arguendo*, that one of ordinary skill in the art were to combine the disclosures of Dereume *et al.* with Clapper, as suggested by the Examiner, the result would be either an endoluminal graft (per Dereume *et al.*) or a vascular graft (per Clapper) having a mechanical means for anchoring the graft to a desired location (per Dereume *et al.*) and specific adhesion molecule(s) covalently bound to the porous surface of the graft (per Clapper), where the adhesion molecules were present at a concentration effective to achieve capillary endothelization. In contrast, and quite unlike to combination of Dereume *et al.* and Clapper, the present invention is directed to a stent graft that releases an agent which induces the *in vivo* adhesion of the stent graft to vessel walls. Applicants respectfully submit that the mere fact that the teachings of the prior art *can* be combined or modified, or that a person having ordinary skill in the art is *capable* of combining or modifying the teachings of the prior art, does not make the

resultant combination *prima facie* obvious, as the prior art must also suggest the desirability of the combination (*see, e.g., In re Mills*, 16 U.S.P.Q.2d 1430, Fed. Cir. 1990; *In re Fritch*, 23 U.S.P.Q.2d 1780, Fed. Cir. 1992). In this case, the combination of Dereume *et al.* and Clapper fails to teach or suggest the desirability of forming a stent graft according to Applicants' claimed invention.

Furthermore, the cited references do not supply the requisite reasonable expectation of success, in that the proposed modification to arrive at the instant invention would render Clapper unsatisfactory for it intended purpose. That is, Clapper requires that the disclosed adhesion molecules be covalently immobilized to a graft in order to promote mechanical attachment of cells to the substrate. Thus, a person having ordinary skill in the art would not be motivated to combine Dereume *et al.* and Clapper to arrive at the instantly claimed stent graft that releases an agent which induces *in vivo* adhesion because the Clapper invention would be rendered inoperable. It is well established that if a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). Moreover, neither Dereume *et al.* nor Clapper teach or suggest induction of *in vivo* adhesion, or induction or acceleration of an *in vivo* fibrotic reaction. Thus, the combined cited prior art cannot possibly render the claimed invention obvious.

Applicants also submit that when prior art references require a selective combination to render obvious a subsequent invention, there must be some reason for the combination *other* than the hindsight gleaned from the invention itself. Furthermore, as set forth in the instant specification and as noted in the Office Action, adhesive agents were known in the art (*see* specification at page 8, lines 19-28; *see also* Ken and Cahalan *et al.* cited in the Office Action, which references are merely cumulative art to those already disclosed in the instant specification), as were stent grafts (*see* specification at page 7, line 5 through page 8, line 2) at the time of filing the instant application. However, to combine known components and optimize the same for a use that is neither suggested nor implicit in the art, such as a stent graft that releases an agent which induces *in vivo* adhesion, cannot be regarded as obvious (*see In re Geiger*, 2 U.S.P.Q.2d 1276, Fed. Cir. 1987). Here, the Examiner simply invokes the skill in the

art, but fails to provide a cogent explanation as to how or why a person having ordinary skill in the art could possibly arrive at the claimed stent grafts in view of Dereume *et al.* and Clapper, and even in view of Ken and Cahalan *et al.*

In sum, Applicants respectfully submit that the Examiner has failed to set forth a *prima facie* case of obviousness. In particular, no evidence has been provided that, at the time of filing the instant application, a person having ordinary skill in the art would have been motivated to arrive at the claimed invention with a reasonable expectation of success, given the disclosures of the cited references. Accordingly, Applicants respectfully submit that the Patent Office fails to meet its initial burden of factually supporting a *prima facie* case of obviousness and, therefore, request that this rejection be withdrawn.

(b) In the Office Action, claims 1-17 and 30-36 were rejected under 35 U.S.C. §103(a) as obvious over U.S. Patent No. 5,723,004 (Dereume *et al.*) in view of U.S. Patent No. 5,744,515 (Clapper), and further in view of U.S. Patent No. 5,948,427 (Yamamoto *et al.*). In particular, it is alleged that it would have been obvious for a person having ordinary skill in the art to employ an outer coat that delays the *in vivo* adhesion as taught by Yamamoto *et al.* in the vascular graft of Dereume *et al.* in view of Clapper in order to postpone adhesion between the graft and vessel walls according to the instant invention.

Applicants respectfully traverse this ground of rejection and submit that Dereume *et al.*, Clapper and Yamamoto *et al.*, taken alone or in combination, fail to teach or suggest the claimed invention and, further, would not have motivated a person having ordinary skill in the art to arrive at the claimed invention with a reasonable expectation of success. As set forth above, the combination of Dereume *et al.* and Clapper fail to teach or suggest every limitation of the claimed invention. Applicants respectfully submit that the disclosure of Yamamoto *et al.* fails to remedy the deficiencies of Dereume *et al.* and Clapper. Yamamoto *et al.* disclose the use of microcapsules that contain an adhesive and that must be activated to release the adhesive. The instant invention is not so limited. That is, no activation is required for the stent grafts of the instant invention to release an agent that induces *in vivo* adhesion. Thus, the combined cited prior art still cannot possibly render the claimed invention obvious.

Applicants respectfully submit that the Office Action has not set forth a *prima facie* case of obviousness, where the cited references fail to teach every limitation of the instant invention and fail to provide motivation for a person having ordinary skill in the art to modify or combine the prior art teachings to arrive at the claimed invention with a reasonable expectation of success. Accordingly, Applicants respectfully submit that the claims distinguish patentably over Dereume *et al.*, Clapper and Yamamoto *et al.*, and, therefore, satisfy the requirements of 35 U.S.C. § 103(a). Applicants request that this rejection be withdrawn.

The Commissioner is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

All of the pending claims in the application are now clearly allowable. Favorable consideration and a Notice of Allowance are earnestly solicited. The Examiner is urged to contact the undersigned attorney if there are any questions prior to allowance of this matter.

Respectfully submitted,
Lindsay S. Machan *et al.*
Seed Intellectual Property Law Group PLLC

CUSTOMER NO.
00500

Jeffrey C. Pepe, Ph.D.
Registration No. 46,985

(JCP:lmp) 430220v2

Phone: (206) 622-4900
Fax: (206) 682-6031